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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/485,438 | 06/07/95 | EISENBERG | S 65850-1103.2 |

18M2/0430

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EXAMINER

MOORE, W

ART UNIT

PAPER NUMBER

1814

DATE MAILED: 04/30/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

08/485,438

Applicant(s)

Eisenberg et al.

Examiner

William W. Moore

Group Art Unit

1814



☒ Responsive to communication(s) filed on Dec 26, 1996

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 12 and 13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 12 and 13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8, 9 & 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicant's Amendment B, Paper No. 11, filed December 26, 1996, has been entered and claims 1-11 canceled at Applicant's request rendering the several rejections stated in Paper No. 7 mailed June 26, 1996, moot. Applicant's Information Disclosure Statements filed May 10 and 15, 1996, and January 10, 1997 have been entered as
5 Papers Nos. 9, 8 and 12, respectively; references cited therein were previously considered in the prosecution of the parent application Serial No. 08/209,040 and are, in some instances, duplicative of references cited with Paper No. 7. The executed PTO Forms 1449 accompanying this communication are lined through where citation of a reference would have resulted in its duplication on the face of the patent. Newly-submitted claims
10 12 and 13 describe subject matters of claims 1 and 3 of U.S. Patent No. 5,532,215 to Ledzey et al. to the extent they are drawn to a protease inhibitor which is a human secretory leukocyte protease inhibitor [SLPI]. No determination can be made on the present record whether or not the characteristics described in claims 4 and 5 of the '215 Patent - binding with a viral aspartic protease, a target cell of a viral aspartic protease, or
15 inhibition of proteolytic cleavage of a viral *gag-pol* precursor protein - are shared by a native human SLPI, by the SLPI variants disclosed herein, or by SLPI variants disclosed in U.S. Patent No. 4,760,130 to Thompson et al., incorporated by reference at page 5 of the instant specification.

20 Claims 12 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While Applicant has incorporated the pertinent recitations of claims 1 and 3 of the '215 patent to Ledzey et al. in setting forth claims 12 and 13 herein, both claims
25 incorporate the term "human-type" that is ambiguous, thus indefinite, because there is no definition provided for the term in either specification and there is no art-accepted definition of human-type in the fields of biology or physiology with respect to secreted or circulatory human polypeptides generally, or secreted or circulatory human protease inhibitors specifically. The instant specification indicates that a native human protease

inhibitor and several analogs disclosed in the prior art or in the instant specification may be effective in a claimed method of treatment but provides no indication what a "human-type" protease inhibitor might be or that it might be effective.

The artisan cannot understand the full scope of these claims with the requisite degree
5 of clarity to determine "the subject matter which applicant regards as his invention". See, Ex parte Simpson, 218 USPQ 1020, 1021-1022 (Bd. App. 1982). The specification does not permit a determination of Applicant's intent, whether the claims should be construed narrowly, to describe the native SLPI, its inhibitory-loop substitution analogs or single-domain truncation analogs, or more broadly, as in the protease inhibitors of not too
10 distantly-related primates, thus the full scope of these claims is impermissively indefinite. Amending claims 12 and 13 to delete the suffix "-type" now modifying "human" is required in order to overcome this rejection. Applicant may, if desired, further amend both claims to state, after "comprising", "a native secretory leukocyte protease inhibitor or an analog thereof", thus stating subject matter defined by the specification and the art,
15 but such further amendment is not required to place the claims in condition for allowance, thus appropriate for consideration as a count in interference.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).
20 Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened
25 statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

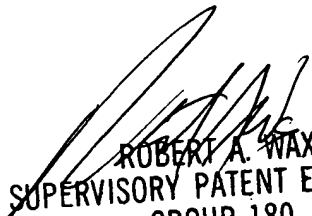
30 Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1 (CM1). Papers may be faxed via the Group Art Unit 1814 direct FAX number (703) 305-7401 in Crystal Mall 1.

Any inquiry concerning this communication or earlier communications from the
35 examiner should be directed to William W. Moore whose telephone number is (703)

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Art Unit: 1814

308-0583. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

5
William W. Moore
April 25, 1997


ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180